February 10, 2023

Vascular Solutions, Inc.
c/o James Chapman
Regulatory Affairs Associate
907 South Lakewood Avenue
Baltimore, Maryland 21224

Re: K073264
Trade/Device Name: D-Stat® Dry Clear, Hemostatic Bandage
Regulatory Class: Unclassified
Product Code: QSX

Dear James Chapman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 7, 2007. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSX.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Solutions, Inc.
% Mr. James Chapman
Regulatory Affairs Associate
907 South Lakewood Avenue
Baltimore, Maryland 21224

DEC 7 2007

Re: K073264
Trade/Device Name: D-State® Dry Clear Hemostatic Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 19, 2007
Received: November 20, 2007

Dear Mr. Chapman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K073264

Device Name: **D-Stat® Dry Clear Hemostatic Bandage**

Indications for Use:

The D-Stat Dry Clear is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing a 4-6 Fr. introducer sheath.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073264

Special 510(k) Summary
(As required by 21 CFR 807.92(c))

Special 510(k) Number: K073264

Date Prepared: **November 19, 2007**

DEC 7 2007

Submitter Information

Submitter's Name: Vascular Solutions, Inc.
Address: 6464 Sycamore Court
Minneapolis, MN 55369

Establishment Registration: 2134812

Contact Person: James Chapman
Regulatory Affairs Associate
Phone: (763) 656-4300 ext. 380
Fax: (763) 656-4253

Device Information

Trade Name: D-Stat® Dry Clear, Hemostatic Bandage
Common Name: Topical hemostat
Classification Name: Unclassified
Product Code: FRO
Regulation: Not Applicable

Predicate Device
The predicate device is the currently marketed D-Stat® Dry Topical Hemostat (K030836).

Device Description
The D-Stat® Dry Clear Hemostatic Bandage consists of a lyophilized pad containing bovine-derived thrombin as an aid to hemostasis (King Pharmaceutical license number 0977), sodium carboxymethylcellulose (CMC), and calcium chloride. Included is a transparent sterile bandage attached to the primary packaging to apply over the hemostatic pad. The only difference between the D-Stat® Dry Clear Hemostatic Bandage and the predicate is the replacement of the opaque sterile bandage included with the device with a transparent sterile bandage.

The D-Stat® Dry Clear is applied directly over the source of bleeding, creating a physical barrier to blood flow through the application of adjunctive manual compression. The lyophilized components (thrombin, CMC, and calcium chloride) establish an environment in which a natural blood clot can build and form a physical barrier to bleeding.

K073264

The thrombin facilitates hemostasis by enhancing the surface-activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin. This fundamental scientific technology is exactly the same as the predicate D-Stat Dry hemostatic bandage.

Intended Use/Indications for Use
The D-Stat Dry Clear has the same indications for use and is intended to be used in the same manner as the predicate D-Stat Dry. The D-Stat Dry Clear is applied topically as an adjunct to manual compression and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes and reducing the time-to-hemostasis in patients undergoing diagnostic endovascular procedures utilizing a 4-6 Fr. introducer sheath.

Summary of Design Control Activities
The risk analysis method used to assess the impact of the modification to the device was a Failure Modes and Effects Criticality Analysis. Based on the results of the risk assessment, no design verification tests were required for inclusion of the sterile clear compression bandage to the D-Stat Dry Clear device.

A declaration of conformity with design controls is included in **Section 7**.

Summary of Clinical Testing
No human clinical testing was required for this device.

Statement of Equivalence
The D-Stat® Dry Clear Hemostatic Bandage and the currently marketed D-Stat® Dry Hemostatic Bandage have the following commonalities:

- Both have the same indicated use,
- Both use the same operating principle
- Both incorporate the same basic device design,
- Incorporate the same materials,
- Have the same shelf life, and
- Are packaged and sterilized using the same materials and processes

Conclusion
In summary, the D-Stat® Dry Clear Hemostatic Bandage is substantially equivalent to the currently marketed D-Stat® Dry Hemostatic Bandage based on a comparison of the indications for use and the technological characteristics of the device.